

DETAILED ACTION

1. This action is responsive to the preliminary amendment filed on January 24, 2006. Claims 10 are pending. Claims 1 and 2 are independent.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Claims 2-10 are objected to because of the following informalities:
 - a. In line 2 of preamble of Claim 2, the term "with" should be replaced by "comprising:."
 - b. In line 12 of Claim 2, the term "have" should be replaced by "has."
 - c. In the preamble of Claims 2-10, the term "device" should be replaced by "system."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to Claims 1, 2, 4, 5, 7, and 9, the term "which" is confusing and being unclear to which structure the term refers throughout each claim.

Regarding Claims 1, 2, and 4, the word "means" is preceded by the word(s) "operator" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Regarding Claims 1, 2, and 9, the word "means" is preceded by the word(s) "actuating" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim 2 recites the limitations "the outside" and "the inside" in lines 12 and 13 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In regard to Claim 4, the recitation "each clip (3) for its connection to the pull cable (21) on its rear end crosspiece (9) connecting the legs (5) has two adjacent through holes (11) through which the pull cable (21) is guided in a loop" is being unclear

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whether the crosspiece or the legs has two adjacent through holes and is being unclear whether the pull cable goes through the crosspiece, legs, or the two adjacent through holes. Examiner interprets that the crosspieces has two adjacent through holes and that the pull cable goes through the crosspiece.

6. Claim 5 recites the limitation "the section" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (US Pub. No.: 2002/0128667).

In regard to Claim 1, Kobayashi et al discloses a method for endoscopic application of self-closing medical clips (combination of 3 and 10, Figs. 21A-21D, 10 is considered as part of the clip since it are left in the body along with 14 after the clip is deployed in the body), especially for stopping internal hemorrhages, in which a catheter tube (1, Figs. 21A-21D) with its distal end is placed in the body of the living being to be treated (Para.[0163]), several clips (Figs. 21A-21D) which are arranged in succession in the catheter tube are advanced by an operator means located on the proximal end of the catheter tube (Para.[0163], there must be a operator means located on the proximal end of the catheter tube for extruding the compression member 11 in the distal end

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direction.) against its distal end, the frontmost clip to be applied is pushed out of the distal end and is opened by an actuating means (combination of manipulating wire 9 and clip tightening ring 29, Figs. 21A-21D) which has an actuating element (manipulating wire 9) which acts on the frontmost clip, which can be moved longitudinal in the catheter tube (Figs. 21A-21D and Para.[0165], the manipulating wire can be moved longitudinal in the catheter tube) and which can be actuated from the operator means (Paras. [0092], [0096], and [0163]-[0166], as the compression member moves, the manipulating wire would be moved and actuated), and has a control part (beveled distal end of 29 acts as a control part, Fig. 19) converting its actuating force into an opening motion of the legs of the clip (Paras.[0165]-[0166] and Figs. 21A-21D), and the actuating element after opening of the clip is detached from the clip in order to release it for the closing of its legs which effects the application and is functionally linked to the clip following in the catheter tube (Paras.[0165]-[0167] and Figs. 21A-21D).

In regard to Claims 2-6, 8, and 9, Kobayashi et al discloses a system, comprising a catheter tube (1, Fig. 21A), an operator means (Para.[0163], there must be a operator means located on the proximal end of the catheter tube for extruding the compression member 11 in the distal end direction.), a pull cable (manipulating wire, 9, Fig. 21A) having a loop (Fig. 21A, the loop of the manipulating wire 9 connects the proximal end of 10), an actuating mean comprising a beveled control surface (beveled surface of clip tightening ring 29, Figs. 19 and 22A) and a tube/plunger (compression member, 11, Fig. 21A), a sleeve-like receiving part (clip tightening ring, 29, Fig. 21A), a clip (14, Fig. 21A) having two adjacent legs, each leg has a first kink (see Fig. 1' below), a second kink

(see Fig. 1' below), and a distal leg end (see Fig. 1' below), and a rear end crosspiece (ligating wire, 10, Fig. 21A), the rear end crosspiece has two adjacent through holes (see Fig. 2' below) and a predetermined breaking point (see Fig. 7C and Fig. 2' below, the predetermined breaking point is located between the through holes.), the pull cable passing through the crosspiece (Fig. 21A) has an advancing strand (either strand of the manipulating wire 9, Fig. 21A) and a retreating strand (the other strand of the manipulating wire 9, Fig. 21A); several clips inside the catheter tube (Fig. 21A); and the pull cable is guided in each case through one or the other through hole of the crosspieces of all the clips (Figs. 21A-21D); and a blocking element (the tapered distal end tip 2 on the distal end of the catheter tube 1 is capable of permitting passage of the 29 with the respective clip only in the exit direction forward but against the motion affected by the pulling force of the manipulating wire 9) on the distal end of the catheter tube.

Claim Rejections - 35 USC § 103

9. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al (US Pub. No.: 2002/0128667) as applied to claim 6 above, and further in view of Kimura et al (US Pub. No.: 2002/0045909).

In regard to Claims 7 and 10, Kobayashi et al discloses all the limitations as taught in Claim 6 and further discloses a collet (distal end tip, 2, Fig. 21A) and an axially projecting shoulder (expansion pieces, 31b, Fig. 22D, the expansion pieces is capable of centering in the collet-like end part of distal tip end) located at the back end of the

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sleeve-like receiving part. However, Kobayashi et al does not appear to disclose that the collet has longitudinal jaws.

However, Kimura et al explicitly teaches a collet (coil pipe, 13, Fig. 7A) for attaching to the distal end of a catheter tube of a clip applier has longitudinal jaws (arm sections, 13d, Fig. 7A).

Kobayashi et al and Kimura et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Kobayashi et al and Kimura et al before him or her, to modify the collet of Kobayashi et al to include the jaws as taught by Kimura et al.

The suggestion/motivation for doing would have been to allow the diameter of the smaller diameter section (Kimura et al, 13a, Fig. 7A) to be expanded and contracted (Kimura et al, Para.[0162]). It is also old and well known in the art that such jaws would provide a more flexibility to the collet having a solid ring.

Therefore, it would have been obvious to combine Kimura et al with Kobayashi et al to obtain the invention as specified in the instant claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kimura et al (US Pat. No.: 6,814,742)

Muramatsu et al (US Pat. No.: 6,923,818)

Kobayashi et al (US Pat. No.: 7,011,667)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

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